DOC930013

FINAL

DATA EVALUATION REPORT

TREO TM SPF 15, 3-Way Protecting Lotion

Study Type: Primary Dermal Irritation in Rabbits

Prepared for:

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DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-5 and 152-14: Primary dermal irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox. Chem. Number: 21901
MRID Number: 421513-08

TEST MATERIAL: TREO TM SPF 15, 3-way protecting lotion

SYNONYMS: Oil of Citronella

SPONSOR: Primavera Laboratories, Inc., 950 Third Avenue, New York, NY

STUDY NUMBER: 90033-1

TESTING FACILITY: Consumer Product Testing Company, Inc., 12 Spielman Road, Fairfield, NJ

TITLE OF REPORT: Primary Dermal Irritation in Rabbits

AUTHOR: Steven Nitka

STUDY COMPLETED: February 23, 1990

CONCLUSIONS: When applied dermally to the skin of albino rabbits, TREO TM SPF 15, 3-way protecting lotion is a non-irritant to intact skin and non-toxic to the cellular components of abraded skin.

CORE CLASSIFICATION: Core Supplementary. This study was classified as Core Supplementary as defined by Guideline (81-5 and 152-14) requirements for an acute dermal irritation study in rabbits because purity and stability data on the test material were not reported. This study could be upgraded pending submission of purity/stability data. Although the average scores obtained for each effect on each test site (one intact and one abraded site) indicate that the test material is non-irritating to the skin, the observation period could have been extended beyond 72 hours in order to determine if the well-defined erythema (noted in 2 of 6 rabbits) was reversible.

TOXICITY CATEGORY: Not applicable

A. MATERIALS

1. Test Material

Test material: TREO TM SPF 15, 3-way protecting lotion
Purity: Not reported
Physical description: Off-white lotion (as reported in an acute dermal study (MRID# 421513-05).
Lot number: Not reported
Storage conditions: Not reported
Stability: Not reported

2. Controls

Animals: None needed
Test substance: None needed

3. Test Animals

Species: Rabbit
Strain: New Zealand white
Source: Not reported-- study author indicated that animals were obtained from a suitably licensed dealer.
Sex: Unspecified
Numbers: Six
Housing: Individual
Acclimation: At least 4 days
Age: Three months
Weight: ≈2 kg
Feeding: Feed (Agway Pro-Pet Big Red Rabbit Feed) and water provided ad libitum.
Selection: Animals in good condition and with healthy intact skin were chosen.

4. Exposure

Route of administration: Dermal
Dose level: 0.5 mL

B. TEST PERFORMANCE

Twenty-four hours prior to exposure, fur was removed from the mid-dorsal area of the trunk, between the scapulae and the pelvis. Prior to dosing, two test sites (each 2.5 cm^2) were chosen on opposite sides of the vertebral column. The test site on the left side of each animal remained intact, while the test site on the right side of each animal was abraded with a needle. The abrasions penetrated the stratum corneum but did not cause bleeding. A single dose of 0.5 mL of the test article was applied to each site. The test article was applied as received. The test sites were then covered with 5 cm^2 gauze pad and held in place with hypo-allergenic cloth tape. The entire trunk of each animal was encased in an impermeable plastic occlusive wrapping taped with porous tape. This held the test article in place and prevented the evaporation of possible volatile components in the test article. Twenty-four hours after application, all wrappings were removed. The remaining test article was removed with water and paper towels. Using the Draize scoring system, each test site was examined and scored for erythema and edema at 24 and 72

hours. The average scores for intact skin and abraded skin were evaluated separately (see Appendix, Tables 1 and 2).

C. RESULTS AND STUDY AUTHOR'S CONCLUSIONS

Intact skin. By 24 hours, 3 of 6 rabbits had very slight erythema (grade 1). All 6 rabbits had very slight to well-defined erythema (grades 0-1) by 72 hours. No edema was seen at 24 hours; 2 of 6 animals had very slight edema (grade 1) by 72 hours.

Abraded skin. By 24 hours, 3 of 6 animals had very slight erythema (grade 1). By 72 hours, 5 of 6 animals had very slight to well-defined erythema. By 24 hours, 1 rabbit had very slight edema (grade 1) and by 72 hours, 2 rabbits had very slight edema.

The primary dermal irritation scores are indicated below:

		Erythema		Edema	
Skin Status	Animal Number	24 Hours	72 Hours	24 Hours	72 Hours
Intact	1	0	1	0	1
	2	0	1	0	0
	3	1	1	0	0
	4	0	2	0	1
	5	1	2	0	0
	6	1	1	0	0
Abraded	1	0	1	0	1
	2	1	0	1	0
	3	0	2	0	0
	4	0	2	0	1
	5	1	2	0	0
	6	1	1	0	0

The study author calculated the average irritation scores for both intact and abraded skin for 24 hours and 72 hours. The scores are indicated below:

	Irritation Scores	
	24 Hours	72 Hours
Intact Skin	0.25	0.83
Abraded Skin	0.33	0.83

Based on these irritation scores, the study author concluded that the compound is a non-irritant for intact skin and is non-toxic to the cellular components of abraded skin.

D. QUALITY ASSURANCE MEASURE

A signed Quality Assurance Statement was presented, but not dated. A Good Laboratory Practice compliance statement was included.

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E. REVIEWERS' COMMENTS

The size of the test site (2.5 cm^2) was less than the Guideline recommendation of 6.0 cm^2. Based on the average scores obtained for each effect on each test site (one intact and one abraded site), the test material is a non-irritant to the intact skin and non-toxic to cellular components for abraded skin. Although the average scores obtained for each effect on each test site indicate that the test material is non-irritating to the skin, the observation period could have been extended beyond 72 hours in order to determine if the well-defined erythema (noted in 2 of 6 rabbits) was reversible. The reviewers also note that the Quality Assurance Statement was signed, but not dated.

This study was classified as Core Supplementary as defined by Guideline (81-5 and 152-14) requirements for an acute dermal irritation study in rabbits because purity and stability data on the test material were not reported. This study could be upgraded pending submission of the purity/stability data.

F. APPENDIX

APPENDIX

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Pages 7 through 8 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

X FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.